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JC614 U.S. PTO

PTO/SB/05 (12/97)

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No. 98-5295 Total Pages

First Named Inventor or Application Identifier

J.T. Lin

Express Mail Label No.

jc542 U.S. PTO
09/18/96 09

11/10/98

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
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<p>1. <input checked="" type="checkbox"/> Fee Transmittal Form <i>(Submit an original, and a duplicate for fee processing)</i></p> <p>2. <input checked="" type="checkbox"/> Specification [Total Pages 22] <i>(preferred arrangement set forth below)</i></p> <ul style="list-style-type: none"> - Descriptive title of the Invention - Cross References to Related Applications - Statement Regarding Fed sponsored R & D - Reference to Microfiche Appendix - Background of the Invention - Brief Summary of the Invention - Brief Description of the Drawings (<i>if filed</i>) - Detailed Description - Claim(s) - Abstract of the Disclosure <p>3. <input checked="" type="checkbox"/> Drawing(s) (35 USC 113) [Total Sheets 3]</p> <p>4. Oath or Declaration [Total Pages]</p> <ul style="list-style-type: none"> a. <input checked="" type="checkbox"/> Newly executed (original or copy) b. <input type="checkbox"/> Copy from a prior application (37 CFR 1.63(d)) <i>(for continuation/divisional with Box 17 completed)</i> <i>(Note Box 5 below)</i> <ul style="list-style-type: none"> i. <input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b). <p>5. <input type="checkbox"/> Incorporation By Reference (<i>useable if Box 4b is checked</i>) The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.</p>	<p>6. <input type="checkbox"/> Microfiche Computer Program (<i>Appendix</i>)</p> <p>7. Nucleotide and/or Amino Acid Sequence Submission <i>(if applicable, all necessary)</i></p> <ul style="list-style-type: none"> a. <input type="checkbox"/> Computer Readable Copy b. <input type="checkbox"/> Paper Copy (identical to computer copy) c. <input type="checkbox"/> Statement verifying identity of above copies
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ACCOMPANYING APPLICATION PARTS

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| <p>8. <input type="checkbox"/> Assignment Papers (cover sheet & document(s))</p> <p>9. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney
<i>(when there is an assignee)</i></p> <p>10. <input type="checkbox"/> English Translation Document (<i>if applicable</i>)</p> <p>11. <input type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations</p> <p>12. <input type="checkbox"/> Preliminary Amendment</p> <p>13. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503)
<i>(Should be specifically itemized)</i></p> <p>14. <input checked="" type="checkbox"/> Small Entity <input type="checkbox"/> Statement filed in prior application, Statement(s) <input type="checkbox"/> Status still proper and desired</p> <p>15. <input type="checkbox"/> Certified Copy of Priority Document(s)
<i>(if foreign priority is claimed)</i></p> <p>16. <input type="checkbox"/> Other:</p> |
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17. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:

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ADDITIONAL FEES <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Large Entity Fee Code (\$)</th> <th>Small Entity Fee Code (\$)</th> <th>Fee Description</th> <th>Fee Paid</th> </tr> </thead> <tbody> <tr><td>105</td><td>130</td><td>205 65 Surcharge - late filing fee or oath</td><td><input type="text"/></td></tr> <tr><td>127</td><td>50</td><td>227 25 Surcharge - late provisional filing fee or cover sheet.</td><td><input type="text"/></td></tr> <tr><td>139</td><td>130</td><td>139 130 Non-English specification</td><td><input type="text"/></td></tr> <tr><td>147</td><td>2,520</td><td>147 2,520 For filing a request for reexamination</td><td><input type="text"/></td></tr> <tr><td>112</td><td>920*</td><td>112 920* Requesting publication of SIR prior to Examiner action</td><td><input type="text"/></td></tr> <tr><td>113</td><td>1,840*</td><td>113 1,840* Requesting publication of SIR after Examiner action</td><td><input type="text"/></td></tr> <tr><td>115</td><td>110</td><td>215 55 Extension for reply within first month</td><td><input type="text"/></td></tr> <tr><td>116</td><td>400</td><td>216 200 Extension for reply within second month</td><td><input type="text"/></td></tr> <tr><td>117</td><td>950</td><td>217 475 Extension for reply within third month</td><td><input type="text"/></td></tr> <tr><td>118</td><td>1,510</td><td>218 755 Extension for reply within fourth month</td><td><input type="text"/></td></tr> <tr><td>128</td><td>2,060</td><td>228 1,030 Extension for reply within fifth month</td><td><input type="text"/></td></tr> <tr><td>119</td><td>310</td><td>219 155 Notice of Appeal</td><td><input type="text"/></td></tr> <tr><td>120</td><td>310</td><td>220 155 Filing a brief in support of an appeal</td><td><input type="text"/></td></tr> <tr><td>121</td><td>270</td><td>221 135 Request for oral hearing</td><td><input type="text"/></td></tr> <tr><td>136</td><td>1,510</td><td>138 1,510 Petition to institute a public use proceeding</td><td><input type="text"/></td></tr> <tr><td>140</td><td>110</td><td>240 55 Petition to revive - unavoidable</td><td><input type="text"/></td></tr> <tr><td>141</td><td>1,320</td><td>241 660 Petition to revive - unintentional</td><td><input type="text"/></td></tr> <tr><td>142</td><td>1,320</td><td>242 660 Utility issue fee (or reissue)</td><td><input type="text"/></td></tr> <tr><td>143</td><td>450</td><td>243 225 Design issue fee</td><td><input type="text"/></td></tr> <tr><td>144</td><td>670</td><td>244 335 Plant issue fee</td><td><input type="text"/></td></tr> <tr><td>122</td><td>130</td><td>122 130 Petitions to the Commissioner</td><td><input type="text"/></td></tr> <tr><td>123</td><td>50</td><td>123 50 Petitions related to provisional applications</td><td><input type="text"/></td></tr> <tr><td>126</td><td>240</td><td>126 240 Submission of Information Disclosure Stmt</td><td><input type="text"/></td></tr> <tr><td>581</td><td>40</td><td>581 40 Recording each patent assignment per property (times number of properties)</td><td><input type="text"/></td></tr> <tr><td>146</td><td>790</td><td>246 395 Filing a submission after final rejection (37 CFR 1.129(a))</td><td><input type="text"/></td></tr> <tr><td>149</td><td>790</td><td>249 395 For each additional invention to be examined (37 CFR 1.129(b))</td><td><input type="text"/></td></tr> <tr><td colspan="4" style="padding: 5px;">Other fee (specify) _____</td></tr> <tr><td colspan="4" style="padding: 5px;">Other fee (specify) _____</td></tr> <tr> <td colspan="2" style="padding: 5px; text-align: right;">SUBTOTAL (1) (\$)</td> <td colspan="4" style="padding: 5px; text-align: right;">395.00</td> </tr> <tr> <td colspan="2" style="padding: 5px; text-align: right;">SUBTOTAL (2) (\$)</td> <td colspan="4" style="padding: 5px; text-align: right;">44.00</td> </tr> <tr> <td colspan="2" style="padding: 5px; text-align: right;">Reduced by Basic Filing Fee Paid</td> <td colspan="4" style="padding: 5px; text-align: right;">SUBTOTAL (3) (\$)</td> </tr> <tr> <td colspan="6" style="padding: 5px; text-align: right;">Complete (if applicable)</td> </tr> <tr> <td colspan="2" style="padding: 5px;">Submitted By</td> <td colspan="2" style="padding: 5px;"></td> <td colspan="2" style="padding: 5px;">Reg. Number</td> </tr> <tr> <td colspan="2" style="padding: 5px;">Typed or Printed Name</td> <td colspan="2" style="padding: 5px;">William M. Hobby, III</td> <td colspan="2" style="padding: 5px;">24,167</td> </tr> <tr> <td colspan="2" style="padding: 5px;">Signature</td> <td colspan="2" style="padding: 5px;">Hobby</td> <td>Date</td> <td>11-6-98</td> </tr> <tr> <td colspan="2" style="padding: 5px;">Deposit Account User ID</td> <td colspan="4" style="padding: 5px;"></td> </tr> </tbody></table>				Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid	105	130	205 65 Surcharge - late filing fee or oath	<input type="text"/>	127	50	227 25 Surcharge - late provisional filing fee or cover sheet.	<input type="text"/>	139	130	139 130 Non-English specification	<input type="text"/>	147	2,520	147 2,520 For filing a request for reexamination	<input type="text"/>	112	920*	112 920* Requesting publication of SIR prior to Examiner action	<input type="text"/>	113	1,840*	113 1,840* Requesting publication of SIR after Examiner action	<input type="text"/>	115	110	215 55 Extension for reply within first month	<input type="text"/>	116	400	216 200 Extension for reply within second month	<input type="text"/>	117	950	217 475 Extension for reply within third month	<input type="text"/>	118	1,510	218 755 Extension for reply within fourth month	<input type="text"/>	128	2,060	228 1,030 Extension for reply within fifth month	<input type="text"/>	119	310	219 155 Notice of Appeal	<input type="text"/>	120	310	220 155 Filing a brief in support of an appeal	<input type="text"/>	121	270	221 135 Request for oral hearing	<input type="text"/>	136	1,510	138 1,510 Petition to institute a public use proceeding	<input type="text"/>	140	110	240 55 Petition to revive - unavoidable	<input type="text"/>	141	1,320	241 660 Petition to revive - unintentional	<input type="text"/>	142	1,320	242 660 Utility issue fee (or reissue)	<input type="text"/>	143	450	243 225 Design issue fee	<input type="text"/>	144	670	244 335 Plant issue fee	<input type="text"/>	122	130	122 130 Petitions to the Commissioner	<input type="text"/>	123	50	123 50 Petitions related to provisional applications	<input type="text"/>	126	240	126 240 Submission of Information Disclosure Stmt	<input type="text"/>	581	40	581 40 Recording each patent assignment per property (times number of properties)	<input type="text"/>	146	790	246 395 Filing a submission after final rejection (37 CFR 1.129(a))	<input type="text"/>	149	790	249 395 For each additional invention to be examined (37 CFR 1.129(b))	<input type="text"/>	Other fee (specify) _____				Other fee (specify) _____				SUBTOTAL (1) (\$)		395.00				SUBTOTAL (2) (\$)		44.00				Reduced by Basic Filing Fee Paid		SUBTOTAL (3) (\$)				Complete (if applicable)						Submitted By				Reg. 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**STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR**

 Docket Number (Optional)
98-5295
Applicant, Patentee, or Identifier: J.T. Lin

Application or Patent No.: _____

Filed or Issued: _____

Title: TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS USING
A DUAL-LASER SCANNING SYSTEM

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

- the specification filed herewith with title as listed above.
 the application identified above.
 the patent identified above.

I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- No such person, concern, or organization exists.
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Separate statements are required from each named person, concern, or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

J.T. Lin
 NAME OF INVENTOR

NAME OF INVENTOR

NAME OF INVENTOR

Signature of inventor

Signature of inventor

Signature of inventor

11-6-98

Date

Date

Date

**TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS
USING A DUAL-LASER SCANNING SYSTEM**

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to methods and apparatus for the treatment of presbyopia and the treatment and prevention of glaucoma using dual-beam scanning lasers.

7. 2. Prior Art

Corneal reshaping, including a procedure called photorefractive keratectomy (PRK) and a new procedure called laser assisted in situ keratomileusis, or laser intrastroma keratomileusis (LASIK), has been performed by lasers in the ultraviolet (UV) wavelength of 193 - 213 nm. Commercial UV refractive lasers include ArF excimer lasers at 193 nm and other non-excimer, solid-state lasers, such as the one patented by the present inventor in 1992 (U.S. Patent No. 5,144,630).

Precise, stable corneal reshaping requires lasers with strong tissue absorption (or minimum penetration depth) such that the thermal damage zone is at a minimum (less than few microns). Furthermore, accuracy of the procedure of vision correction depends on the amount of tissue removed in each laser pulse, in the order of about 0.2 microns. Therefore, lasers at UV wavelengths between 193 and 213 nm and at the mid-infrared wavelengths between 2.8 and 3.2 microns are two attractive wavelength ranges which match the absorption peak of protein and water, respectively.

The above-described prior arts are however limited to the use of reshaping the corneal surface curvature for the correction of myopia and hyperopia.

1 A variation of farsightedness that the existing laser
2 surgery procedures will not treat is presbyopia, the
3 gradual age related condition of suddenly fuzzy print
4 and the necessity of reading glasses. When a person
5 reaches a certain age (around 40), the eyes start to
6 lose their capability to focus sharply for near
7 vision. Presbyopia is not due to the cornea but comes
8 about as the lens loses its ability to accommodate or
9 focus sharply for near vision as a result of loss of
10 elasticity that is inevitable as people age.

11 Thermal lasers such as Ho:YAG have been proposed
12 for the correction of hyperopia by laser-induced
13 coagulation of the corneal. The present inventor has
14 also proposed the use of a laser-generated bifocal for
15 the treatment of presbyopic patients but fundamental
16 issues caused by age of presbyopic patients still
17 remains unsolved in those prior approaches.

18 To treat presbyopic patients, or the reversal of
19 presbyopia, using the concept of expanding the sclera
20 by mechanical devices has been proposed by Schaker in
21 U.S. patents 5,529,076, 5,722,952, 5,465,737 and
22 5,354,331. These mechanical approaches have the
23 drawbacks of complexity and are time consuming, costly
24 and have potential side effects. To treat presbyopia,
25 the Schaker patents Nos. 5,529,076 and 5,722,952
26 propose the use of heat or radiation on the corneal
27 epithelium to arrest the growth of the crystalline
28 lens and also propose the use of lasers to ablate
29 portions of the thickness of the sclera. However,
30 these prior arts do not present any details or
31 practical methods or laser parameters for the
32 presbyopic corrections. No clinical studies have been
33 practiced to show the effectiveness of the proposed
34 concepts. The concepts proposed in the Schaker

1 patents regarding lasers suitable for expanding the
2 sclera tissues were incorrect in that the proposed
3 lasers did not identify those which are "cold lasers"
4 and can only conduct the tissue ablation rather than
5 thermal burning of the cornea. Furthermore, the
6 clinical issues, such as accuracy of the sclera tissue
7 removal and potential tissue bleeding during the
8 procedures, were not indicated in these prior patents.

9 In addition, it is essential to use a scanning laser
10 to achieve the desired ablation pattern and to control
11 the ablation depth on the sclera tissue.

12 One objective of the present invention is to
13 provide an apparatus and method to obviate these
14 drawbacks in the above Schaker patents.

15 It is yet another objective of the present
16 invention to provide an apparatus and method which
17 provide the well-defined laser parameters for
18 efficient and accurate sclera expansion for
19 presbyopia reversal and the treatment and preventing
20 of open angle glaucoma.

21 It is yet another objective of the present
22 invention to use a scanning device such that the
23 degree of ciliary muscle accommodation can be
24 controlled by the location, size and shapes of the
25 removed sclera tissue.

26 It is yet another objective of the present
27 invention to define the non-thermal lasers for
28 efficient tissue ablation and thermal lasers for
29 tissue coagulation. This system is able to perform
30 both in an ablation mode and in a coagulation mode for
31 optimum clinical outcomes. It is yet another
32 objective of the present invention to provide an
33 integrated system in which dual-beam lasers can be
34 scanned over the corneal surface for accurate ablation

1 of the sclera tissue without bleeding, with ablation
2 and coagulation laser beams simultaneously applied on
3 the cornea.

4 It is yet another objective of the present
5 invention to define the optimal laser parameters and
6 the ablation patterns for best clinical outcome for
7 presbyopia patients, where sclera expansion will
8 increase the accommodation of the ciliary muscle.

9 It is yet another objective of the present
10 invention to provide the appropriate scanning patterns
11 which will cause effective sclera expansion.

12

13 SUMMARY OF THE INVENTION

14

15 The preferred embodiments of the present surgical
16 laser consists of a combination of an ablative-type
17 laser and a coagulative-type laser. The ablative-type
18 laser has a wavelength range of from 0.15 to 0.35
19 microns and from 2.6 to 3.2 microns and is operated in
20 a Q-switch mode such that the thermal damage of the
21 corneal tissue is minimized. The coagulative-type
22 lasers includes a thermal laser having a wavelength of
23 between 0.45 and 0.9 microns and between 1.5 and 3.2
24 microns, and between 9 and 12 microns operated at a
25 long-pulse or continuous-wave mode.

26 It is yet another preferred embodiment of the
27 present invention to provide a scanning mechanism to
28 effectively ablate the sclera tissue at a controlled
29 depth by beam overlapping.

30 It is yet another preferred embodiment of the
31 present invention to provide an apparatus and method
32 such that both the ablative and the coagulative lasers
33 can have applied to their beams the corneal surface to
34 thereby prevent bleeding during the procedure.

1 It is yet another embodiment of the present
2 invention to provide an integration system in which a
3 coagulative laser may have the beam delivered by a
4 scan or by a fiber-coupled device which can be
5 manually scanned over the cornea. It is yet another
6 embodiment of the present invention to focus the laser
7 beams in a small circular spot or a line pattern.

8 It is yet another embodiment of the present
9 invention to provide a coagulative laser to prevent
10 the sclera tissue bleeding when a diamond knife is
11 used for the incision of the sclera.

12 It is yet another embodiment of the present
13 invention to use a metal mask on the corneal surface
14 to generate a small slit when the laser is scanning
15 over the mask. In this embodiment, the exact laser
16 spot size and its propagating stability are not
17 critical.

18 It is yet another embodiment of the present
19 invention to provide an integration system in which
20 the sclera expansion leads to the increase of the
21 accommodation of the ciliary muscle for the treatment
22 of presbyopia and the prevention of open angle
23 glaucoma.

24 Further preferred embodiments of the present
25 invention will become apparent from the description of
26 the invention which follows.

27

28 BRIEF DESCRIPTION OF THE DRAWINGS

29

30 Figure 1 is a block diagram of an integrated
31 laser system consisting of two lasers of different
32 wavelengths coupled to the cornea by mirrors and a
33 scanning device;

34

1 Figure 2 is a block diagram of a laser system
2 where the coagulative laser is fiber-coupled and
3 manually delivered to the cornea;

4 Figure 3 is the schematic drawing of the
5 anteroposterior section through the anterior portion
6 of a human eye, where the sclera and ciliary muscle
7 are shown; and

8 Figures 4A-4D are diagrams of the possible
9 ablation patterns which will achieve a presbyopia-
10 reversal.

11

12 DETAILED DESCRIPTION OF THE INVENTION AND THE
13 PREFERRED EMBODIMENTS

14

15

16 Figure 1 of the drawings is a schematic of a
17 laser system having an ablative laser 1 producing a
18 laser beam 2 of a predetermined wavelength and focused
19 by a lens 3 onto a reflecting mirror 4 which is
20 coupled to another reflecting mirror 5. The system
21 also consists of a coagulation laser 6 having a laser
22 beam 7 of a predetermined wavelength focused by a
23 lens 3A through a mirror 5. The ablation laser 1 beam
24 2 and the coagulation laser 6 beam 7 are directed onto
25 a scanner 8. The beams 2 and 7 are then reflected by
26 a mirror 9 onto the cornea 10 of a patient's eye. The
27 scanner 8 consists of a pair of motorized coated
28 mirrors with a 45 degree highly reflecting both the
29 ablative laser beam 2 and the coagulative laser beam
30 7. The mirror 4 and mirror 9 are highly reflective to
31 the wavelength of the beams 2 and 7. Mirror 5 is
32 coated such that it is highly reflective of laser beam
33 2 but highly transparent to laser beam 7. The
34 focusing lens 3 has a focal length of about 10-100 cm
35 such that the spot size of the ablative laser beam 2
36 is about 0.1-0.8 mm on the corneal surface. The

1 focusing lens 3A also has a focal length about 10-100
2 cm such that the spot size of the coagulative laser
3 beam 7 is about 0.2-2.0 mm on the corneal surface. In
4 Figure 1, both the ablative and the coagulative lasers
5 beams 2 and 7 are scanned by the scanner 8 over the
6 corneal sclera area of the eye 10 to generate
7 predetermined patterns, as shown in Figure 4. In
8 Figure 1, the said coagulative laser 6 is used to
9 prevent the potential bleeding during the ablation
10 process of the sclera tissue. Typically, the
11 coagulative laser 6 beam 7 has a spot size larger than
12 the ablative laser 1 beam 2 and has an average power
13 in the range of 20-3000 mW, depending upon the size of
14 the focused beam. To achieve an effective
15 coagulation, the temperature increase of the sclera
16 tissue produced by the coagulative laser beam 7 should
17 be in the range of 40-70 degree Centigrade. The
18 preferred embodiment of the laser 1 and 6 includes a
19 pulsed ablative laser with a pulse width less than 200
20 nanoseconds such as a Er:YAG laser; Er:YSGG laser; an
21 optical parametric oscillation (OPO) at 2.6-3.2
22 microns; a gas laser with a wavelength of 2.6-3.2
23 microns; an excimer laser of ArF at 193 nm; a XeCl
24 laser at 308 nm; a frequency-shifted solid state laser
25 at 0.15 - 3.2 microns; a CO laser at about 6.0 microns
26 and a carbon dioxide laser at 10.6 microns. The long
27 pulse coagulative lasers have a pulse longer than 200
28 nanoseconds of a green laser; or an argon laser; or a
29 Ho:YAG at 2.1 microns; or a Er:glass at 1.54 microns;
30 or an Er:YAG; or an Er:YSGG; or a diode laser at 0.8-
31 2.1 microns, or any other gas lasers at 0.8-10.6
32 microns. To achieve the ablation of the sclera tissue
33 at the preferred laser spot size of 0.1-0.8 mm
34 requires an ablative laser energy per pulse of about

1 0.1-5.0 mJ depending on the pulse duration. On the
2 other hand, the coagulative laser should have an
3 average power of about 30 mW for a small spot and
4 about to 3 W for a larger spot.

5 Referring to Figure 2, an alternative schematic
6 for the coagulative laser 6 is coupled to a fiber 11
7 for delivery of the beam to the cornea, where a line
8 pattern may be performed by manually scanning the beam
9 over the cornea. Alternatively, a fiber-coupled
10 coagulation laser 6 may be focused by a cylinder lens
11 to form a line spot on the cornea where a typical spot
12 size of 0.2-2.0 mm x 3.0 -5.0 mm is preferred. In
13 Figure 2, the ablative laser 1 has the same schematic
14 as that of Figure 1 where the laser beam 2 is coupled
15 to the scanner 8 and reflected by the mirror 9 onto
16 the cornea. An alternative embodiment of the present
17 invention is to use a cylinder lens to focus the
18 ablative laser 1 to a line spot with a size of 0.1-0.8
19 mm x 3.0 - 5.0 mm on the corneal surface to eliminate
20 the scanner 8. Another embodiment may use an optical
21 fiber or an articulate arm to deliver both the
22 coagulative and ablative laser beams such that the
23 presbyopia treatment may be conducted manually without
24 the need of a scanner or reflecting mirrors.

25 Figure 3 shows the lens of a human eye 12
26 connected to the ciliary body 13 and the sclera 14 by
27 zonule fibers 15. Expansion of the sclera 14 will
28 cause the ciliary muscle to contract and the lens
29 becomes more spherical in topography with a shorter
30 radii of curvature for near objects. The reversed
31 process of ciliary muscle relaxation will cause a
32 longer radii of curvature for distant objects.
33 Therefore, laser ablation of the sclera tissue will
34 increase the accommodation of the ciliary body for the

1 presbyopic patient to see both near and distance. For
2 efficient sclera expansion, the depth of the laser
3 ablation needs to be approximately 80% - 90% of the
4 sclera thickness which is about 500 - 700 microns.
5 For safety reasons, the ablation depth should not cut
6 through the choroid. It is therefore clinically
7 important that the patient's sclera thickness be
8 measured pre-operatively and the laser ablation depth
9 controlled. A scanning laser is used to control this
10 depth by the number of scanning lines or slots over
11 the selected area at a given set of laser parameters.
12 Pre-operatively, PMMA is used to calibrate the depth
13 of tissue ablation. Alternatively, the surgeon may
14 observe the color change of the ablated sclera tissue
15 to determine when the ablation depth reaches the
16 interface of the sclera and the ciliary.

17 Figure 4 shows examples of ablation patterns
18 which will cause sclera expansion and increase the
19 accommodation of the presbyopic patient. As shown in
20 Figure 4A, line patterns are conducted between
21 circles 16 and 17 which have diameters of about 8-11
22 mm and 12-15 mm, respectively. The width of the
23 ablated lines are about 0.1-0.5 mm with a depth of
24 80%-90% of the sclera. Eight (8) lines are shown in
25 Figure 4A as an example but it can be more or less
26 without departing from the spirit and scope of the
27 invention. Enhancement may be performed by adding
28 more ablation lines. Figure 4B shows a ring pattern
29 with a diameter 18 of about 12-14 mm. A two-ring
30 pattern 19 is shown in Figure 4C where two circles
31 have diameters of about 10 mm and 12 mm, respectively.
32 Another example of an ablation pattern is shown in
33 Figure 4D where the ablation laser is focused to a
34 round spot 20 of about 0.1-0.5 mm in diameter and

1 scanned over the sclera area to form an eight spot
2 symmetric ring which has a diameter of about 12-14 mm.
3 In all the above described ablative patterns, the
4 coagulative laser described in Figures 1 and 2
5 simultaneously deliver these patterns such that the
6 sclera tissue may be coagulated as the tissue is being
7 ablated. The preferred spot sizes of the coagulative
8 lasers are larger than that of the ablative laser so
9 that the alignment of the coagulative laser is not
10 critical.

11 Another embodiment of controlling the ablation
12 area of the sclera area is to use a metal mask which
13 has a plurality of slits each having an approximate
14 dimension of 0.1-0.3 mm x 3.0-5.0 mm. Both of the
15 ablative and coagulative lasers will scan over the
16 mask which is placed on the corneal surface to
17 generate the desired slit pattern on the sclera. In
18 this embodiment using a mask, the small laser spot
19 sizes of 0.1 mm, which may be difficult to achieve,
20 are not needed in order to generate the slit size on
21 the cornea. Laser spot sizes of 0.2-1.0 mm will
22 generate the desired ablation dimension on the sclera
23 after scanning over the mask. Furthermore, the
24 embodiment of using a mask will not require a precise
25 stability of the laser beam path onto the corneal
26 surface. Without using a mask, both the exact laser
27 beam spot size and its stability in propagating would
28 be essential.

29 Another embodiment of sclera expansion of the
30 present invention is to use diamond knife for the
31 incision of the sclera tissue in the patterns
32 described in Figures 4A, 4B and 4C where the
33 coagulation laser is simultaneously applied onto the
34 cut tissue to prevent bleeding. The incision depth

1 should be about 80% to 90% of the sclera thickness in
2 order to achieve the effects of sclera expansion.
3 Accordingly, the pre-operative measurement of the
4 sclera thickness is essential for the knife incision
5 procedure and surgeon's skill is more important than
6 that of using an ablative laser, in which the ablation
7 depth of the sclera tissue is well controlled by the
8 numbers of scanning lines in a given pattern. We are
9 able to calibrate the ablation rate of various lasers
10 on the sclera tissue by comparing the clinical data
11 and that of the selected materials including a PMMA
12 plastic sheet.

13 The invention having now been fully described, it
14 should be understood that it may be embodied in other
15 specific forms or variations without departing from
16 the spirit or essential characteristics of the present
17 invention. Accordingly, the embodiments described
18 herein are to be considered to be illustrative and not
19 restrictive.

I claim:

1 1. A laser beam ophthalmological surgery method
2 for treating presbyopic in a patent's eye by ablating
3 the sclera comprising the steps of :

4 selecting a pulsed ablation laser having a pulsed
5 output beam of predetermined wavelength and an energy
6 per pulse of between 0.1 - 5 mJ on the surface of the
7 cornea;

8 selecting a beam spot controller mechanism for
9 reducing and focusing said selected ablative laser's
10 output beam onto a predetermined spot size on the
11 surface of the cornea;

12 selecting a scanning mechanism for scanning said
13 ablative laser output beam;

14 coupling said ablative laser beam to a scanning
15 device for scanning said ablative laser over a
16 predetermined area of the corneal sclera; and

17 controlling said scanning mechanism to deliver
18 said ablative laser beam in a predetermined pattern in
19 said predetermined area onto the surface of the
20 cornea to photoablate the sclera, whereby a presbyopic
21 patient's vision is corrected by expansion of the
22 sclera.

1 2. A laser beam ophthalmological surgery method
2 for treating presbyopic in a patent's eye by ablating
3 the sclera in accordance with claim 1 in which the
4 step of selecting a pulsed ablation laser includes
5 selecting a pulsed ablative laser having a
6 predetermined wavelength between 0.15 - 0.32 microns.

1 3. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 ablating the sclera in accordance with claim 1 in
4 which the step of selecting a pulsed ablation laser
5 includes selecting a pulsed ablative laser having a
6 wavelength between 2.6 and 3.2 microns.

1 4. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 ablating the sclera in accordance with claim 1 in
4 which the step of selecting a pulsed ablation laser
5 includes selecting a Q-switched solid state laser
6 having a pulse duration shorter than 200 nanoseconds.

1 5. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 ablating the sclera in accordance with claim 1 in
4 which the step of selecting a pulsed ablation laser
5 includes selecting a pulsed gas laser having a pulse
6 duration shorter than 200 nanoseconds.

1 6. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 ablating the sclera in accordance with claim 1 in
4 which said the step of selecting a beam spot
5 controller includes selecting a pulsed ablative laser
6 having a focusing lens with focal length of between
7 10 and 100 cm selected to obtain a predetermined laser
8 beam spot size having a diameter of between 0.1 and
9 0.8 mm on the corneal surface.

1 7. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by 6g
3 ablating the sclera in accordance with claim 1 in
4 which the step of selecting a beam spot controller
5 includes selecting beam spot controller having a
6 focusing lens with cylinder focal length of between 10
7 and 100 cm to obtain a laser beam spot having a line
8 size of about 0.1-0.8 mm x 3-5 mm on the corneal
9 surface.

1 8. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 ablating the sclera in accordance with claim 1 in
4 which the step of selecting a scanning mechanism
5 includes selecting a scanning mechanism having a pair
6 of reflecting mirrors mounted to a galvanometer
7 scanning mechanism for controlling said laser output
8 beam into a predetermined overlapping pattern.

1 9. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 ablating the sclera in accordance with claim 8 in
4 which the step of selecting said scanning mechanism
5 includes selecting a scanning mechanism having an
6 overlapping pattern overlapping from 20 to 80% within
7 the selected area of the sclera.

1 10. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 ablating the sclera in accordance with claim 1
4 including the steps of:

5 selecting a coagulative laser having a
6 pulsed output beam of predetermined wavelength; and

7 directing said selected coagulative laser
8 onto those areas of the sclera photoablated with the
9 selected pulsed ablation laser.

1 11. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 ablating the sclera in accordance with claim 10
4 including the steps of:

5 selecting a metal mask having at least one
6 slit therein; and

7 positioning the selected mask over the
8 cornea surface for scanning the ablation laser and
9 the coagulative laser thereover for controlling the
10 ablation slit pattern on the sclera.

1 12. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patient's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue including
5 the steps of:

6 selecting an ablation laser having an output
7 beam of predetermined wavelength for ablating the
8 surface of the cornea;

9 ablating a predetermined area of the cornea
10 sclera with the output beam from said ablation laser;

11 selecting a coagulative laser having an
12 pulsed output beam of predetermined wavelength having
13 an average power of between 20-3000 mW on the surface
14 of the cornea;

15 selecting a beam spot controller mechanism for
16 reducing and focusing said coagulative laser beam to
17 a predetermined spot size on the corneal surface;

18 selecting a scanner for scanning said
19 coagulative laser output beam;

20 coupling said coagulative laser beam onto a
21 scanner for scanning said coagulative laser beam over
22 a predetermined area of the corneal sclera which has
23 been ablated by said ablation laser;

24 controlling the scanner to deliver said
25 coagulative laser output beam in a predetermined
26 pattern onto a plurality of positions on the corneal
27 surface to coagulate the ablated areas of the sclera,
28 whereby bleeding in said ablated tissue is reduced by
29 the said coagulation laser beam.

1 13. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 12 in which said predetermined
6 wavelength is between 0.5 and 3.2 microns.

1 14. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 12 in which said predetermined
6 wavelength is between 5.5-10.6 microns.

1 15. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 12 in which said coagulative
6 laser is a continuous wave laser.

1 16. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 12 in which said selected
6 coagulative laser is a long pulse laser having a pulse
7 duration longer than 200 nanoseconds.

1 17. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 12 in which said step of
6 selecting a beam spot controller includes selecting a
7 focusing lens having a focal length of between 10 and
8 100 cm. to obtain a predetermined laser beam spot size
9 having a diameter between 0.2-2.0 mm on the corneal
10 surface.

1 18. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 12 in which said selecting
6 beam spot controller includes a focusing lens having
7 a focal length of between 10 and 100 cm selected to
8 obtain a predetermined laser beam spot having a line
9 size of about 0.2-2.0 x 3-5 mm on the corneal
10 surface.

1 19. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 12 in which the step of
6 selecting a scanning mechanism includes selecting a
7 scanning mechanism having a pair of reflecting mirrors
8 mounted to a galvanometer scanner for controlling said
9 coagulative laser output beam into an overlapping
10 pattern following said ablative laser output beam
11 ablating surface tissue on the corneal surface.

1 20. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 19 in which said overlapping
6 pattern includes an overlap of between 20 and 80% in
7 a pattern defined on the corneal surface by said
8 ablative laser.

1 21. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 12 in which said ablative laser
6 has a wavelength between 0.5-3.2 microns and a pulse
7 width shorter than 200 nanoseconds delivered to the
8 surface of the cornea by an optical fiber.

1 22. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue ablated with an ablating
4 laser beam to prevent bleeding in the tissue in
5 accordance with claim 12 in which said selected
6 coagulative laser has a wavelength of between 0.5-10.6
7 microns, and a pulse width longer than 200 nanoseconds
8 delivered to the surface of the cornea by an optical
9 fiber to prevent tissue bleeding.

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1 23. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue expanded by a knife to
4 prevent bleeding in the tissue including the steps
5 of:

6 cutting a predetermined area of the cornea
7 sclera with a knife;

8 selecting a coagulative laser having an
9 pulsed output beam of predetermined wavelength having
10 an average power of between 20-3000 mW on the surface
11 of the cornea;

12 selecting a beam spot controller mechanism for
13 reducing and focusing said coagulative laser beam to
14 a predetermined spot size on the corneal surface;

15 selecting a scanner for scanning said
16 coagulative laser output beam;

17 coupling said coagulative laser beam onto a
18 scanner for scanning said coagulative laser beam over
19 a predetermined area of the corneal sclera which has
20 been cut with said knife;

21 controlling the scanner to deliver said
22 coagulative laser output beam in a predetermined
23 pattern onto a plurality of positions on the corneal
24 surface to coagulate the cut areas of the sclera,
25 whereby bleeding in said cut tissue is reduced by the
26 said coagulation laser beam.

1 24. A laser beam ophthalmological surgery
2 method for treating presbyopic in a patent's eye by
3 coagulating sclera tissue expanded by a knife to
4 prevent bleeding in the tissue in accordance with
5 claim 23 in which the selected coagulative laser has
6 a wavelength of between 0.5 and 10.6 microns and a
7 pulse width longer than 200 nanoseconds.

**TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS
USING A DUAL-LASER SCANNING SYSTEM**

1 ABSTRACT OF THE DISCLOSURE

2

3 Presbyopia is treated by a method which uses
4 ablative lasers to ablate the sclera tissue and
5 increase the accommodation of the ciliary body.
6 Tissue bleeding is prevented by a dual-beam system
7 which consists of ablative and coagulative lasers.
8 The preferred embodiments of the present invention
9 include a short pulse ablative laser (pulse duration
10 less than 200 nanoseconds) having a wavelength of
11 between 0.15 and 3.2 microns and a long pulse (longer
12 than 200 nanoseconds) coagulative laser having a
13 wavelength range of between 0.5 and 10.6 microns. A
14 scanning system is proposed to perform various
15 patterns on the sclera area of the cornea to treat
16 presbyopia and to prevent other eye disorder such as
17 glaucoma. Laser parameters are determined for accurate
18 sclera expansion.

19

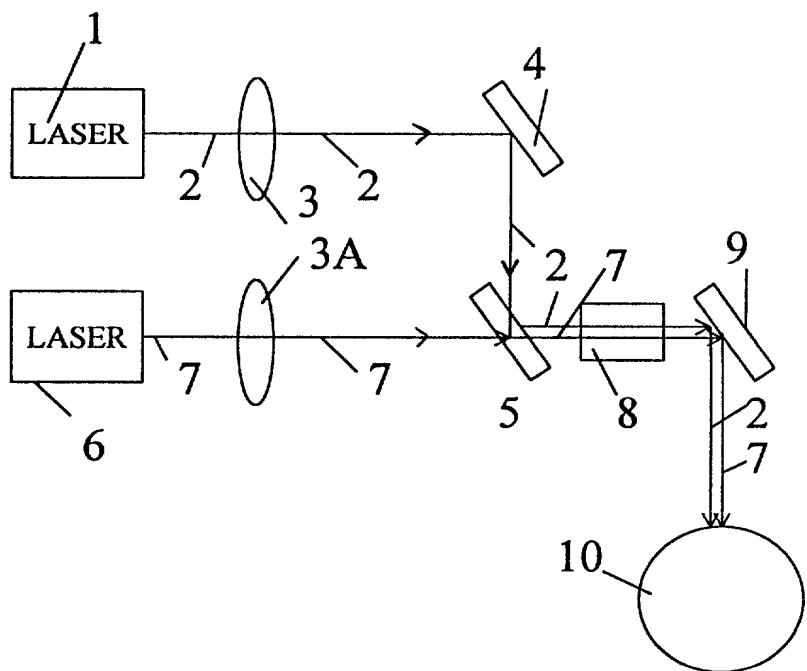


FIG. 1

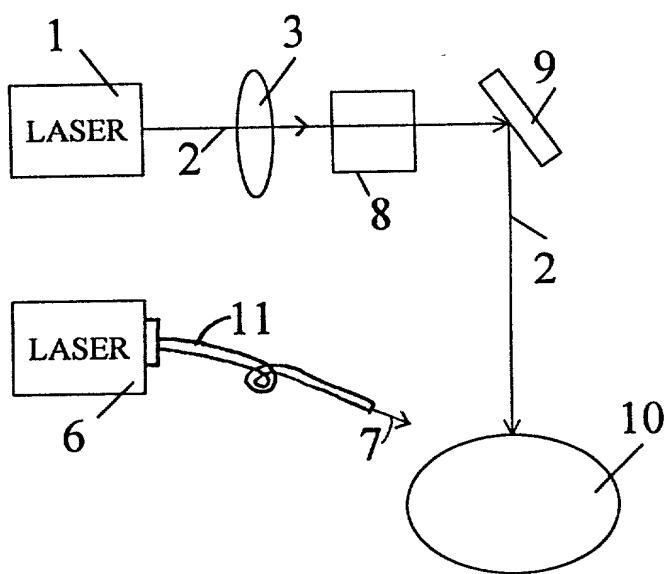


FIG. 2

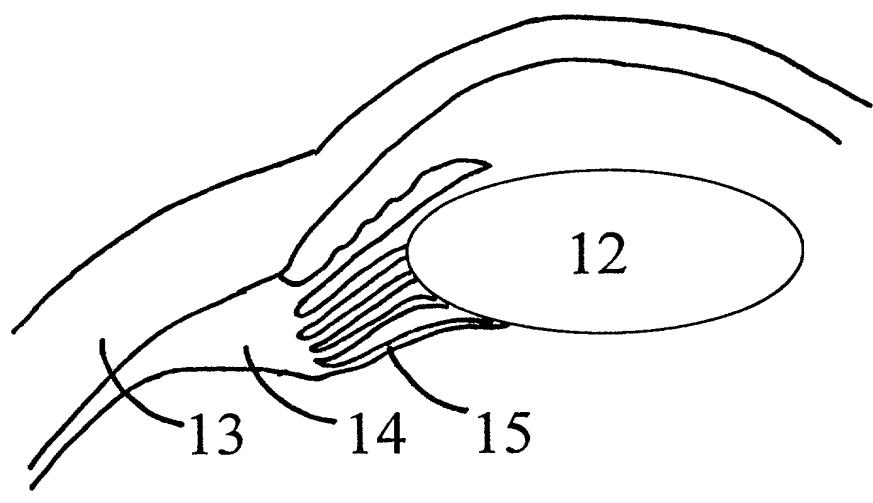


FIG. 3

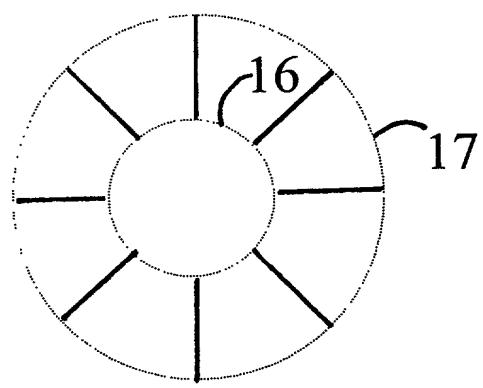


FIG. 4A

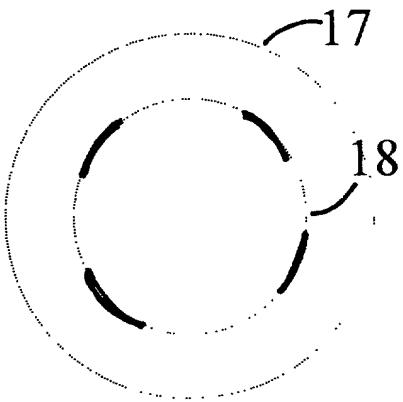


FIG. 4B

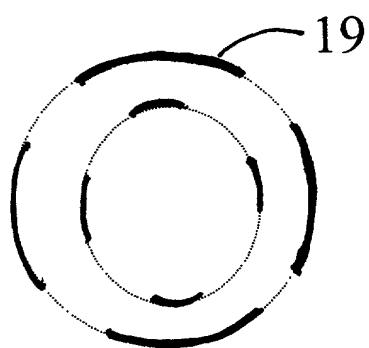


FIG. 4C

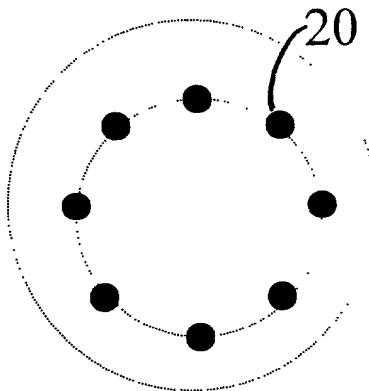


FIG. 4D

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PTO/SB/01 (12-97)

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**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**

Declaration Submitted with Initial Filing OR Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	98-5295
First Named Inventor	J.T. Lin
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS USING
A DUAL-LASER SCANNING SYSTEM**

the specification of which

(Title of the Invention)

is attached hereto

OR

was filed on (MM/DD/YYYY) as United States Application Number or PCT International

Application Number and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	Certified Copy Attached? NO
			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number <i>(if applicable)</i>

Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number → *Place Customer Number Bar Code Label here*
 Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
William M. Hobby, III	24,167		

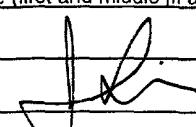
Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto

Direct all correspondence to: Customer Number OR Correspondence address below

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: A petition has been filed for this unsigned inventor

Given Name (first and middle if any)		Family Name or Surname					
J.T.		Lin					
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Additional inventors are being named on the _____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto